

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

1:13-cv-12682; 1:13-cv-12426; 1:13-cv-12688
1:13-cv-12696; 1:13-cv-12738; 1:13-cv-12915
1:13-cv-12838; 1:13-cv-12489; 1:13-cv-12733
1:13-cv-12480; 1:13-cv-12596; 1:13-cv-12840
1:13-cv-12580; 1:13-cv-12836; 1:13-cv-12581
1:13-cv-12666; 1:13-cv-12583; 1:13-cv-12734
1:13-cv-12597; 1:13-cv-12843; 1:13-cv-12759
1:13-cv-12922; 1:13-cv-12428; 1:13-cv-12923
1:13-cv-12918; 1:13-cv-12914; 1:13-cv-12490
1:13-cv-12311; 1:13-cv-12491; 1:13-cv-12998
1:13-cv-12917; 1:13-cv-12619; 1:13-cv-12238

DECLARATION OF BENJAMIN A. GASTEL

Benjamin A. Gastel declares, under penalty of perjury on the date identified below, as follows:

1. I am an attorney at Branstetter, Stranch, and Jennings, PLLC, and the firm sits on the Plaintiffs' Steering Committee ("PSC") in the above-styled lawsuit (the "MDL"). I have been working with many Plaintiffs' counsel in Tennessee in developing and filing claims against the Tennessee Defendants¹ and have personally reviewed many, although not all, of the complaints filed in Tennessee state and federal court. I have personally reviewed documents produced by Tennessee Defendants in state court litigation and in this litigation. I make this Declaration in support of the Plaintiffs' Steering Committee's Rule 56 Response to the Tennessee Defendants' Motion for Summary Judgment.

¹ Any capitalized terms not otherwise defined herein have the same meaning as defined in the contemporaneously filed Rule 56(d) Response to Tennessee Defendants' Motion for Summary Judgment.

2. According to the CDC, the pain clinic known as Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Clinic") purchased MPA from New England Compounding Pharmacy d/b/a New England Compounding Clinic ("NECC"), and was one of three Tennessee clinics to receive confirmed tainted MPA lots from NECC.

3. According to the CDC, the pain clinic known as Specialty Surgery Center purchased MPA from NECC and was one of three Tennessee clinics to receive confirmed tainted lots from NECC.

PSC Attempts To Obtain Discovery To Date From Tennessee Defendants

4. According to MDL Order Number 7 (Dkt. No. 438), the Court permitted discovery over the Tennessee Defendants to begin "forthwith".

5. As early as September 25, 2013, the PSC had requested the Tennessee Defendants to provide dates for 30(b)(6) depositions and provide initial disclosures pursuant to Rule 26. Thereafter, on October 6, 2013 and October 16, 2013, the PSC served common written discovery under Rule 33, 34 and 36 on the Tennessee Defendants. The parties then began meeting and conferring on various issues raised by the formal discovery served and the requests for deposition dates and initial disclosures.

6. On December 30, 2013, the Tennessee Defendants provided certain limited responses to the discovery requests but principally objected to the discovery as untimely, failed to provide initial disclosures, and did not provide dates for any depositions. In short, the Tennessee Defendants initial responses to discovery requests did not contain, with very limited exceptions, meaningful responses and much meeting and conferring on these responses remains to be done. A copy of the discovery responses served by the Tennessee Defendants are attached collectively hereto as Exhibit 1.

7. After further meet and confers, on December 30, 2013, Saint Thomas finally produced the documents they had produced previously in state court litigation. Notwithstanding the limited production, the Tennessee Defendants have not produced emails and other electronically stored information (“ESI”) despite the PSC’s repeated requests that the Tennessee Defendants begin a rolling production of responsive ESI.

8. Accordingly, to date, the sum total of discovery received from the Tennessee Defendants is limited and relatively unresponsive responses to initial discovery requests and a limited document production. The PSC has not taken a single deposition and the Tennessee Defendants have refused to provide dates for such a deposition, and the Tennessee Defendants have not yet produced initial disclosures.

9. Discovery has proceeded slowly against the Tennessee Defendants’ despite the Court’s order to begin discovery, in part, because the Tennessee Defendants moved the Court to reconsider its order opening discovery (Dkt. Nos. 457 and 459). The motion was granted in part and denied in part (Dkt. No. 731), and the parties have been meeting and conferring on the remaining issues (i.e. plaintiff fact sheets, deposition and ESI protocols, etc.) since the Court entered the order granting in part and denying in part the Tennessee Defendants’ motion for reconsideration.

10. The meet and confer letters demonstrating the PSC’s attempts to obtain discovery from the Tennessee Defendants are attached hereto collectively as Exhibit 2.

Tennessee Defendants’ Liability As Sellers Of MPA And Other Pharmaceuticals

11. After reviewing medical billing records for clients from both Saint Thomas Clinic and SSC, it appears that on certain billing statements, that both Saint Thomas Clinic and SSE would charge for the NECC product administered to the patient. It is reasonable to assume that

every patient that received an epidural steroid injection has a correlating billing statement associated with Saint Thomas Clinic and SSC's attempts to collect payment for the procedure and the NECC pharmaceuticals at issue in this litigation. These documents have not been produced in this litigation. Further discovery is needed over patient billing records to determine the extent and scope of both Saint Thomas Clinic and SSC's activities as they relate to selling the pharmaceuticals at issue in this litigation. Copies of billing records available at this time from both Saint Thomas Clinic and SSC are attached hereto as Exhibits 3a and 3b (these billing statements are redacted to protect patient privacy).

12. Further, based on publicly available information from the CDC and FDA, plaintiffs need additional discovery to show that the products sold by Saint Thomas Clinic and SSC were in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller. Pages from both the FDA and CDC website confirming the likelihood of existence of further documents related to these issues are attached hereto as Exhibit 4.

13. Specifically, further discovery from both Saint Thomas Clinic and SSC along with NECC and other defendants will likely demonstrate, that both Saint Thomas Clinic and SSC received confirmed tainted lots of MPA from NECC that contained fungal spores and other microbial sources of contamination and that the products were in a state of contamination when they left the Tennessee Defendants' control.

14. Further, based on the publicly available information from the CDC and FDA, plaintiffs will be able to show that the dangerous products sold by Saint Thomas Clinic and SSC directly caused injuries, and in some instances, death of Saint Thomas Clinic and SSC patients as a result of the contaminated nature of the pharmaceuticals Saint Thomas Clinic and SSC sold to their patients. An article from the New England Journal of Medicine discussing the

epidemiologic and laboratory data from the multistate outbreak of fungal infections associated with injection of contaminated MPA compounded by NECC is attached hereto as Exhibit 5.

Tennessee Defendants' Liability For Civil Conspiracy

15. As outlined in the Amended Master Complaint (Dkt. No. 832), Plaintiffs allege that Saint Thomas Clinic actively participated with NECC in a scheme to avoid the individual prescription requirement in Saint Thomas Clinic's procurement of NECC pharmaceuticals. As alleged in the Amended Master Complaint, Saint Thomas Clinic, and its relevant agents, knew that the Massachusetts law required that individual prescriptions were required to procure pharmaceuticals from NECC. According to the Amended Master Complaint, notwithstanding this requirement, the Saint Thomas Clinic sent NECC a list of patient names even though the list contained names of patients that did not receive NECC products and contained at least one fictitious name. As outlined in the Amended Master Complaint, through the limited discovery taken to date, Plaintiffs have been able to uncover documents that support these allegations. Further discovery is needed to fully understand Saint Thomas Clinic's role in actively participating with NECC in alleged violations of Massachusetts law.

16. Such discovery uncovered to date includes, but is not limited to, Saint Thomas Clinic's admission in sworn discovery responses the following:

Mr. Giamei [an agent of NECC] stopped by STOPNC in early to mid-2012 and spoke with Ms. Schamberg. He informed Ms. Schamberg that NECC needed STOPNC to submit a list of patients with each order. Debra informed Mr. Giamei that STOPNC would not be able to predict which patients would actually receive the MPA, and Mr. Giamei said that that was fine because NECC just needed a list of patient names. Mr. Giamei stated that the requirement came from the Massachusetts Board of Pharmacy. Ms. Schamberg consulted with Dr. Culclasure and a pharmacist prior to sending the list of names. Ms. Schamberg spoke with receptionist Sherri DeZwaan to determine the best way for STOPNC to provide such a list. Ms. DeZwaan suggested printing off the daily patient schedule. For the next several orders, when STOPNC needed to order

MPA, Ms. Littleton asked Ms. DeZwaan to print off a list of names, which she did...

17. From my review of documents produced by other clinics, it also appears that other clinics were similarly aiding NECC's attempts to sell pharmaceuticals without individual prescriptions for each patient receiving NECC compounded pharmaceuticals. Further discovery is needed to fully understand SSC's role in actively participating with NECC in violating Massachusetts law.

Executed on this 24th day of February, 2014, in Nashville, Tennessee.



Benjamin A. Gastel